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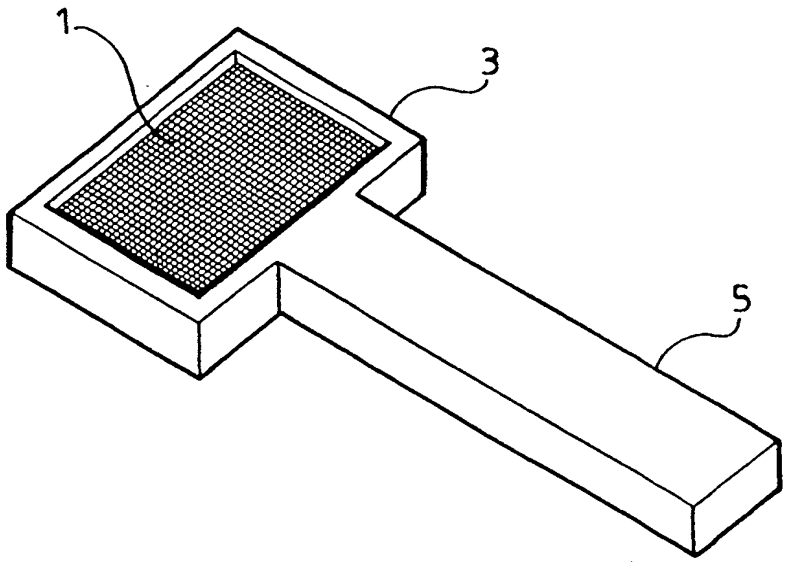
(54) Title: SUPPORT FOR DIAGNOSTIC TESTS

(57) Abstract

A diagnostic test support includes a mesh (1) for supporting a diagnostic test reagent and means (3) for holding the mesh. A diagnostic test device incorporates the support and a diagnostic test reagent. The support is made by providing a sheet of non-adherent material and applying to the sheet a liquid carrier material (7) for a diagnostic test reagent and a mesh (1) for supporting the carrier material. The carrier material (7) is allowed to dry or otherwise solidify and is then removed from the sheet of non-adherent material with the mesh (1) embedded therein, cut to size and mounted in a holder (3).



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SUPPORT FOR DIAGNOSTIC TESTS

This invention relates to a support for diagnostic tests, to a diagnostic test device incorporating the support and to a method of manufacturing the support.

Diagnostic test devices are well known for detecting an analyte in fluids, particularly body fluids. For example, EP-A-0 207 360 describes such a diagnostic test device in which a bibulous (absorbent) material is impregnated with at least one ingredient capable of producing a detectable response upon contact with the fluid. The bibulous material may form a substrate for the test device or it may be in the form of pads mounted on a rigid matrix or substrate. A selectively permeable silicone film is bonded over the bibulous material and to the substrate. EP-A-0 280 560 describes a membrane structure for use in diagnostic tests in which a microporous membrane formed from a biologically inert material, such as a polyamide, is provided with a coating which does not substantially diminish the porosity of the membrane.

These known diagnostic test devices and the supports on which they are based are relatively complex, and therefore costly, to produce and it is desirable to be able to provide a simpler and more cost effective support.

It is therefore an object of the present invention to provide an improved support for diagnostic tests. It is also an object of the present invention to provide a diagnostic test device incorporating such a support and a method of manufacturing such a support.

According to one aspect of the present invention there is provided a diagnostic test support comprising a mesh for supporting a diagnostic test reagent and means for holding the mesh.

The mesh may comprise a polymeric film or fibre material such as polyester, nylon or cellulose, or a paper material. The material of the mesh may be inherently porous or may have pores formed therein.

The material of the mesh may be transparent or coloured, for example white.

The mesh may incorporate pores having dimensions in the range from about 10 microns to about 500 microns, preferably from about 10 microns to about 120 microns.

A layer of carrier for the diagnostic test reagent may be applied to at least one side of the mesh and optionally to both sides thereof. The thickness of the at least one layer of carrier may be in the range from about 10 microns to about 60 microns or more.

The carrier material may comprise a gelatinous material or a polymeric material, such as a resin.

A coating may be applied to the surface of at least one layer of carrier material. The coating may comprise a filter. Alternatively or additionally, the coating may comprise a light reflective material.

The carrier may be provided with a permeable protective layer, such as a mesh. The protective layer may be impregnated with a permeable material.

According to a second aspect of the present invention there is provided a diagnostic test device incorporating a diagnostic test support as defined hereinabove and a diagnostic test reagent.

The diagnostic test reagent may be incorporated into the carrier material or may be applied to a surface thereof.

Alternatively, the diagnostic reagent may be applied directly to the mesh.

According to a third aspect of the present invention there is provided a method of manufacturing a support for a diagnostic test device comprising the steps of:

providing a sheet of non-adherent material;

applying to the sheet of non-adherent material a liquid carrier material for a diagnostic test reagent and a mesh for supporting the carrier material;

allowing the carrier material to dry or otherwise solidify; and

removing the carrier material with the mesh embedded therein from the sheet of non-adherent material, cutting the carrier material and mesh to size and mounting the cut material in a holder.

The sheet of non-adherent material may comprise a sheet of siliconised material.

The liquid carrier material may be applied to the sheet of non-adherent material subsequent to the mesh.

Alternatively, the liquid carrier material may be applied to the sheet of non-adherent material prior to the mesh. In this case a further layer of liquid carrier material may be applied to the mesh. The first-mentioned layer of carrier material may be allowed to dry or otherwise solidify prior to application of the mesh. The further layer of carrier material may be allowed to dry or otherwise solidify prior to removal of the carrier material with the mesh embedded therein from the sheet of non-adherent material.

The diagnostic test reagent may be incorporated into the carrier material or may be applied to a surface thereof.

A permeable protective layer may be applied to the carrier material. The permeable protective layer may comprise a mesh. The protective layer may be impregnated with a permeable material.

For a better understanding of the present invention and to show more clearly how it may be carried into effect reference will now be made, by way of example, to the accompanying drawings in which:

Figure 1 is a diagrammatic perspective view of one embodiment of a diagnostic test support according to the present invention;

Figure 2 is a diagrammatic cross-sectional view through a second embodiment of a diagnostic test support according to the present invention;

Figure 3 is a diagrammatic cross-sectional view through a third embodiment of a diagnostic test support according to the present invention;

Figure 4 is a diagrammatic cross-sectional view through a fourth embodiment of a diagnostic test support according to the present invention; and

Figure 5 is a diagrammatic illustration of a method for manufacturing the diagnostic test support of the present invention.

The diagnostic test support shown in Figure 1 comprises a mesh 1 mounted in a holder 3 which is provided with a handle 5 or other means to facilitate handling of the holder. The holder 3 may be made of any suitable material,

such as a plastics material, the mesh being secured in place by, for example, sandwiching the mesh between upper and lower components of the holder, by ultrasonic welding or by means of a suitable adhesive or the like.

The mesh 1 is made of a material which is porous per se or which is treated so as to be porous. The material of the mesh may be any suitable material including, for example, a polymeric material film or fibre material such as a polyester, nylon, cellulose or paper which is made into a mesh by forming the material into a woven or non-woven fabric, by casting or by forming apertures through a sheet or film material.

The material and construction of the mesh 1 may be selected to confer particular optical properties where these may be necessary or desirable for the diagnostic test to be carried out. For example, the mesh may be transparent or reflective (that is, opaque or white) or may be formed in a specific colour. However, the material of the mesh should ideally be self-supporting over the dimensions thereof (in practice, about 6 mm square) because any substantial bowing of the mesh, and therefore of the support, would increase the likelihood of light scatter influencing the results of the test where a reflectance meter is employed rather than visual comparison with a colour chart.

Generally, the material of the mesh need not be absorbent, but this is not excluded.

The material of the mesh is generally selected so as to be inert with respect to the diagnostic test to be carried out, although the mesh could be loaded with a substance which activates or enhances the chemical reaction of the test. Moreover, the physical properties of the mesh are selected such that the porosity of the mesh exerts no

influence on the test. In this respect, the dimensions of the pores in the mesh may be of the order of from about 10 to about 500 microns, preferably from about 10 to about 120 microns which can be contrasted to a pore size of about 0.5 to 0.6 microns for a microporous support material. In one particular embodiment, a polyester mesh is employed having a pore size of substantially 62 microns.

In the embodiment of Figure 1 a diagnostic test reagent, for example an enzyme such as glucose oxidase, is applied directly to the material of the mesh 1.

The diagnostic test support shown in Figure 2 is similar to that of Figure 1 except that a carrier material 7 for the test reagent is applied to one side of the mesh 1. The diagnostic test support shown in Figure 3 is similar to that shown in Figure 2 except that the carrier material 7 for the test reagent is applied to both sides of the mesh 1.

The carrier material 7 is generally absorbent of the fluid containing the analyte to be tested for, but this is not essential, for example where a surface reaction is to be carried out. The carrier material may comprise, for example a gelatinous material or a polymeric material, such as a resin. The carrier material itself is inert with respect to the diagnostic test to be carried out, but is impregnated with, or otherwise carries, the diagnostic test reagent.

If desired, the carrier material 7 or the mesh 1 may be provided with a surface coating 8. As explained hereinabove, the surface coating could include the diagnostic test reagent, but alternatively the surface coating could function as a filter so as to exclude certain components of the fluid containing the analyte to be tested for. As a further alternative, the coating could include

a light reflective material, such as titanium dioxide powder, so as to enhance any colour change in the diagnostic test reagent. In the case of Figure 3, however, a light reflective material, such as titanium dioxide powder, could be incorporated into the lower layer of carrier material.

It should be noted, however, that the material of the carrier 7 can, under certain circumstances, function as a filter. For example the carrier material can absorb low molecular weight constituents of the fluid containing the analyte, while acting as a barrier to the penetration of, for example, red blood cells.

The thickness of the carrier material 7 has a number of effects. For example, the thickness (and therefore the volume) of the carrier material controls the volume of the sample tested. The thickness additionally influences the intensity of any colour change, thus a relatively thick carrier can be used to enhance any colour change when the analyte is particularly dilute. The thickness of the carrier material also influences the reaction rate, with slower reaction rates for thicker carriers.

It has been found that a surface coating, when provided, especially where the surface coating includes a light reflective material such as titanium dioxide powder, is susceptible to damage if the fluid containing the analyte to be tested for is applied in an abrasive manner. Under certain circumstances, therefore, it may be advantageous to provide a permeable protective cover on at least one surface of the carrier material such as that shown in Figure 4.

The same references are used in Figure 4 as in the other figures to denote the same or similar parts.

As can be seen from Figure 4 a permeable protective layer is applied to one surface of the carrier material 7 and comprises a mesh 9 which is lightly impregnated with a permeable material 11 (that is, a material that is transmissive of the analyte to be tested for).

The mesh 9 may be the same as or different to the mesh 1. That is, the mesh 9 is made of a material which is porous per se or which is treated so as to be porous. The material of the mesh 9 may be any suitable material including, for example, a polymeric material film or fibre material such as a polyester, nylon, cellulose or paper which is made into a mesh by forming the material into a woven or non-woven fabric, by casting or by forming apertures through a sheet or film material.

The impregnating material 11 may comprise, for example, a gelatinous material, such as substantially pure gelatin, or a polymeric material, such as a resin. It has been found that, while the impregnating material is not essential in all cases, it can aid transmission of the fluid containing the analyte through the mesh 9.

By way of example, the diagnostic test support shown in Figure 3 may be made as illustrated diagrammatically in Figure 5. That is, by providing a sheet of material 13 which is non-adherent to the carrier material, such as a sheet of siliconised material, and applying a layer of the liquid carrier material 7 to the sheet. For example, the carrier material may be gelatin and may be applied in a layer having a thickness of about 60 microns when wet. The layer of carrier material is then allow to dry or otherwise solidify, during which process the carrier material may acquire, for example, a degree of porosity. Thus, a 60 micron layer of gelatin will dry to a thickness of about 10 microns. It will be borne in mind the diagnostic test reagent can either be incorporated into the carrier

material or applied subsequently to the surface of the carrier material.

The mesh 1 is then applied to the surface of the carrier material 7 and a second layer of liquid carrier material 7 is applied to the mesh. The second layer of carrier material penetrates the mesh so as to secure the mesh to the first layer of carrier material. The second layer of carrier material may have a similar thickness to the first layer and, once applied, is allowed to dry.

If desired, a layer 8 of coloured or reflective material may be applied to the second layer 7 of carrier material. However, as noted above, such coloured or reflective material could be incorporated into the second layer of carrier material.

When complete, the combination of layers can be removed from the non-adherent sheet material 13, cut to size, and mounted in the holder 3 as shown in Figure 1.

The diagnostic test support shown in Figure 2 is made in a similar way to that of Figure 3, but either the first layer or the second layer of carrier material is omitted and the mesh, if applied to the first layer, may need to be applied before the material of the first layer has fully dried.

The diagnostic test support shown in Figure 4 is also made in a similar way to that of Figure 3, but with an additional step of applying an impregnated mesh to the second layer of carrier material or to the layer 8 applied thereto.

The diagnostic test support shown in Figure 1 is made by applying the diagnostic test reagent to the mesh, cutting the mesh to size, and mounting the mesh in the holder 3.

CLAIMS

1. A diagnostic test support comprising a mesh (1) for supporting a diagnostic test reagent and means (3) for holding the mesh.

2. A diagnostic test support as claimed in claim 1, characterised in that the mesh (1) is selected from polymeric film and fibre material and paper material.

3. A diagnostic test support as claimed in claim 2, characterised in that the polymeric film and fibre material is selected from polyester, nylon and cellulose.

4. A diagnostic test support as claimed in any preceding claim, characterised in that the material of the mesh (1) is inherently porous.

5. A diagnostic test support as claimed in any one of claims 1 to 3, characterised in that the material of the mesh (1) has pores formed therein.

6. A diagnostic test support as claimed in any preceding claim, characterised in that the material of the mesh (1) is transparent.

7. A diagnostic test support as claimed in any one of claims 1 to 5, characterised in that the material of the mesh (1) is coloured, for example white.

8. A diagnostic test support as claimed in any preceding claim, characterised in that the mesh (1) incorporates pores having dimensions in the range from about 10 microns to about 500 microns.

9. A diagnostic test support as claimed in claim 8, characterised in that the mesh (1) incorporates pores

having dimensions in the range from about 10 microns to about 120 microns.

10. A diagnostic test support as claimed in any preceding claim, characterised in that a layer of carrier (7) for the diagnostic test reagent is applied to at least one side of the mesh (1).

11. A diagnostic test support as claimed in claim 10, characterised in that a layer of carrier (7) for the diagnostic test reagent is applied to both sides of the mesh (1).

12. A diagnostic test support as claimed in claim 10 or 11, characterised in that the thickness of the at least one layer of carrier (7) is in the range from about 10 microns to about 60 microns or more.

13. A diagnostic test support as claimed in any one of claims 10 to 12, characterised in that the material of the carrier (7) is selected from a gelatinous material and a polymeric material.

14. A diagnostic test support as claimed in claim 13, characterised in that the material of the carrier (7) comprises a resin.

15. A diagnostic test support as claimed in any one of claims 12 to 14, characterised in that a coating (8) is applied to the surface of at least one layer of carrier material (7).

16. A diagnostic test support as claimed in claim 15, characterised in that the coating (8) comprises a filter.

17. A diagnostic test support as claimed in claim 15 or 16, characterised in that the coating (8) comprises a light reflective material.

18. A diagnostic test support as claimed in any one of claims 10 to 17, characterised in that the carrier (7) is provided with a permeable protective layer (9).

19. A diagnostic test support as claimed in claim 18, characterised in that the protective layer comprises a mesh (9).

20. A diagnostic test support as claimed in claim 18 or 19, characterised in that the protective layer is impregnated with a permeable material (11).

21. A diagnostic test device incorporating a diagnostic test support as claimed in any preceding claim and a diagnostic test reagent.

22. A diagnostic test device as claimed in claim 21, characterised in that the diagnostic test reagent is incorporated into the carrier material (7).

23. A diagnostic test device as claimed in claim 21 or 22, characterised in that the diagnostic test reagent is applied to a surface of the carrier material (7).

24. A diagnostic test device incorporating a diagnostic test device as claimed in any one of claims 1 to 9, characterised in that the diagnostic test reagent is applied directly to the mesh (1).

25. A method of manufacturing a support for a diagnostic test device comprising the steps of:

providing a sheet of non-adherent material;

applying to the sheet of non-adherent material a liquid carrier material (7) for a diagnostic test reagent and a mesh (1) for supporting the carrier material;

allowing the carrier material (7) to dry or otherwise solidify; and

removing the carrier material (7) with the mesh (1) embedded therein from the sheet of non-adherent material, cutting the carrier material and mesh to size and mounting the cut material in a holder (3).

26. A method according to claim 25, characterised in that the sheet of non-adherent material comprises a sheet of siliconised material.

27. A method according to claim 25 or 26, characterised in that the liquid carrier material (7) is applied to the sheet of non-adherent material subsequent to the mesh (1).

28. A method according to claim 25 or 26, characterised in that the liquid carrier material (7) is applied to the sheet of non-adherent material prior to the mesh (1).

29. A method according to claim 28, characterised in that a further layer of liquid carrier material (7) is applied to the mesh (1).

30. A method according to claim 29, characterised in that the first-mentioned layer of carrier material (7) is allowed to dry or otherwise solidify prior to application of the mesh (1).

31. A method according to claim 29 or 30, characterised in that the further layer of carrier material (7) is allowed to dry or otherwise solidify prior to removal of the carrier material (7) with the mesh (1) embedded therein

carrier material (7) with the mesh (1) embedded therein from the sheet of non-adherent material.

32. A method according to any one of claims 25 to 31, characterised in that the diagnostic test reagent is incorporated into the carrier material (7).

33. A method according to any one of claims 25 to 32, characterised in that the diagnostic test reagent is applied to a surface of the carrier material (7).

34. A method according to any one of claims 25 to 33, characterised in that a permeable protective layer (9) is applied to the carrier material (7).

35. A method according to claim 34, characterised in that the permeable protective layer (9) comprises a mesh.

36. A method according to claim 34 or 35, characterised in that the protective layer (9) is impregnated with a permeable material (11).

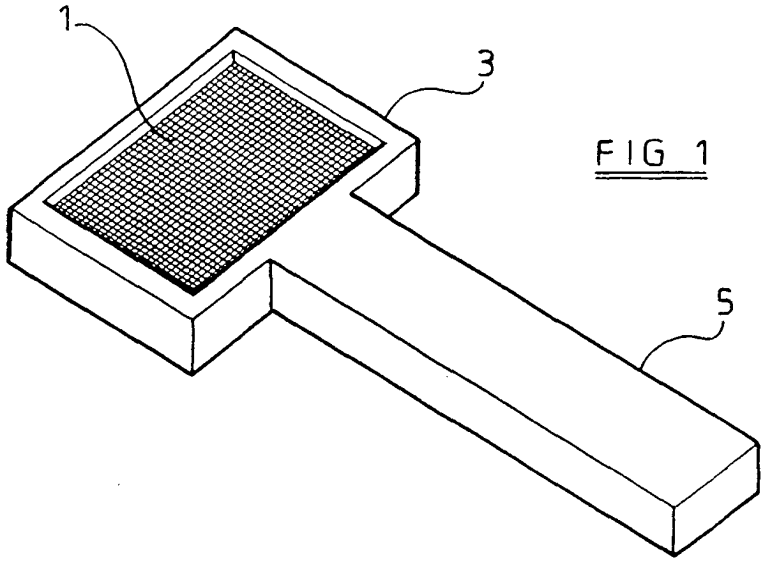

FIG 1

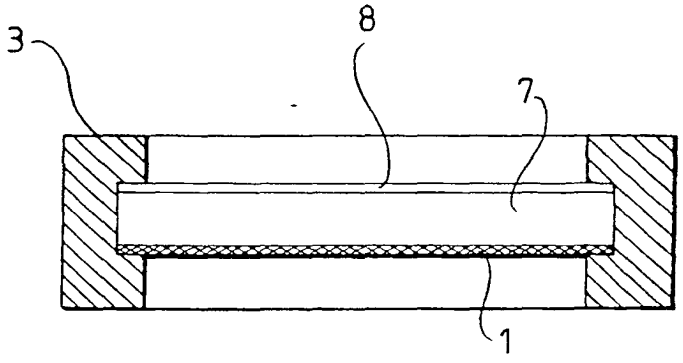

FIG 2

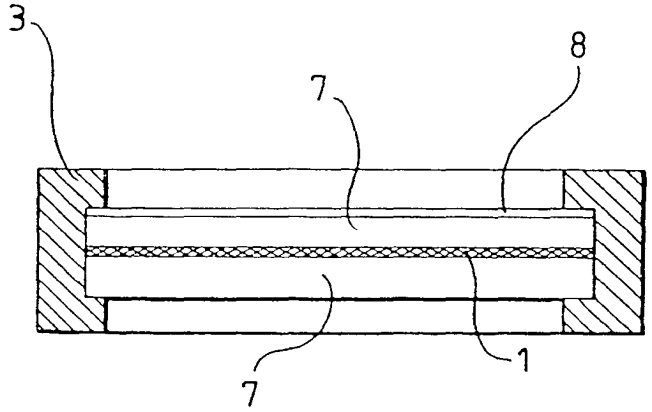

FIG 3

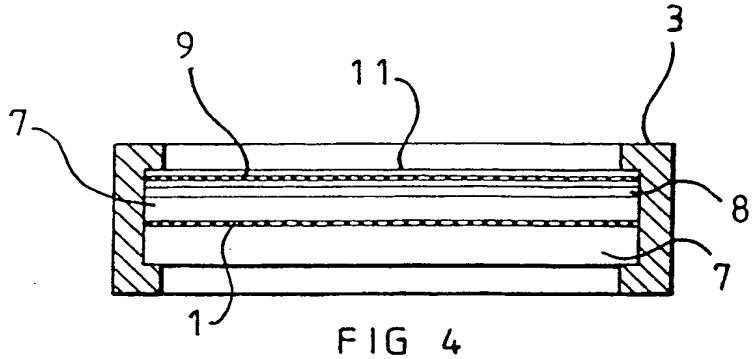

FIG 4

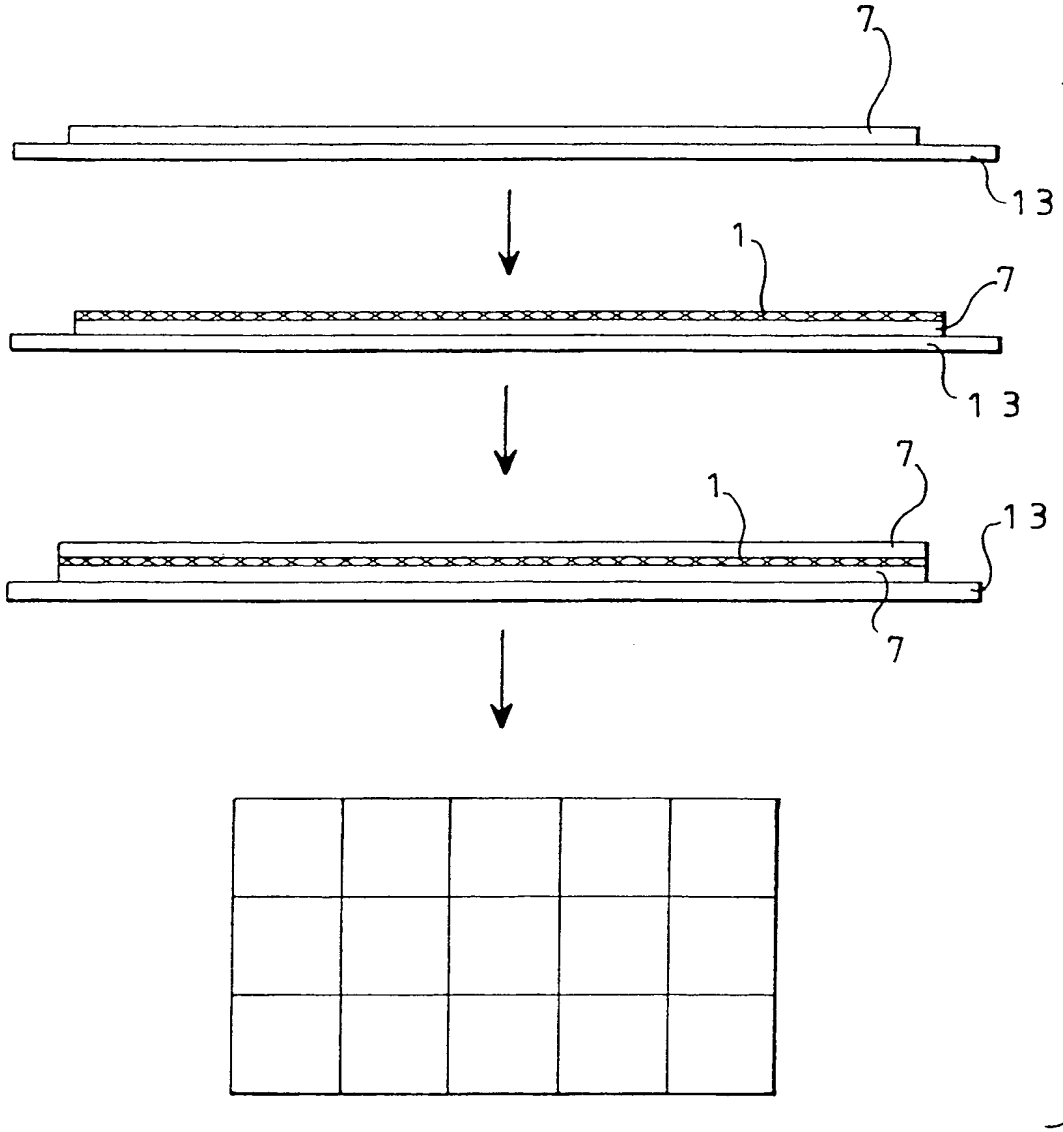

FIG 5

INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 G01N33/52 G01N33/53 G01N33/543

According to International Patent Classification (IPC) or to both national classification and IPC

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Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 588 564 A (AMERSHAM INT PLC) 23 March 1994 see claims 1,3 see column 6, line 42 - column 7, line 10	1-24
Y		25-35

X	WO 93 19372 A (SAFEFOOD MICRO SYSTSM AS) 30 September 1993 see claims 1-4 see page 5, line 37 - page 6, line 6	1-24

X	US 5 595 653 A (GOOD THOMAS J ET AL) 21 January 1997 see claims 1,10,14-17 see column 2, line 18 - line 26	1-24
Y	see column 4, line 10 - line 18	25-35

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category '	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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Y	see claims see column 4, line 56 - line 67	25-35
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